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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,030	04/07/2006	Sanshiro Nagare	283071US0PCT	8330

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,030	NAGARE ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 07/21/2008 to the Office Action mailed on 03/19/2008 is acknowledged.

Status of the Claims

Claims 1-6, 10, and 12 are currently amended and claims 7 and 11 are cancelled. Therefore, claims 1-6, 8-10, and 12 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Bosch et al. (US Patent Application 2002/0102294 A1, Published 08/01/2002).

Bosch et al. teach, "The invention discloses aqueous dispersions of nanoparticulate aerosol formulations, dry powder nanparticulate aerosol formulations. The nanoparticles of the aqueous dispersions or dry powder formulations comprise insoluble drug particles having a surface modifier on the surface thereof." (See abstract). "The compositions of the invention are aerosols which contain drug nanoparticles." (See paragraph 0052). "Preferably, the compositions of the invention contain nanoparticles which have an effective average particle size of less than about 1000 nm, more preferably less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, or less than about 50 nm, as measured by light-scattering methods." (See paragraph 0053). "The nanoparticles of the invention comprise a therapeutic or diagnostic agent, which in the invention are collectively are referred to as 'drug'." (See paragraph 0091). In a preferred embodiment the drug is budesonide. (See paragraph 0151, Example 9A). With regard to the instantly claimed recitation of "nanoparticle produced by a process comprising …", such a limitation is a product by process limitation and is not given patentable weight. "Even though product-by-process claims are limited by the defined the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the product of the prior art, the claim is unpatentable even thought the

prior product was made by a different process." (See *In re Thorpe*, 227 USPQ 964 (Fed. Cr. 1985)). For the foregoing reasons the instant invention is anticipated by the prior art.

Claims 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Feldheim et al. (US Patent 6602932 B2, Published 08/05/2003, Filed 12/15/2000).

Feldheim et al. teach, "Nanoparticle composites …" (See title). "A composition of matter comprising: (a) a nanoparticle template; (b) a shell formed on the nanoparticle template by polymerizing a monomer on the nanoparticle template; and (c) a guest molecule, wherein the nanoparticle template carries the guest molecule and the guest molecule is encapsulated by the shell." (See column 20, claim 1). "… [W]herein said guest molecule is a biologically active agent." (See column 20, claim 2). The active agent "is selected from the group consisting of an immunogenic peptide or protein …" (See column 20, claim 4). "… [W]herein the nanoparticle template comprises material from the group consisting of a metal, a ceramic, an organic polymer, and combinations thereof." (See column 20, claim 7). "... [W]herein said organic polymer comprises a material selected from the group consisting of polystyrene, poly(pyrrole), poly(N-methylpyrrole), poly(ethylenegylcol), and combinations thereof." (See column 20, claim 10). "... [W]herein the nanoparticle template is a sphere having a diameter ranging from about 1 nanometer to about 1,000 nanometers." (See column 20, claim 12). " …[W]herein the nanoparticle template is a sphere having a diameter ranging from about 5 nanometers to about 200 nanometers." (See column 21, claim 13). " …[W]herein the nanoparticle template is a sphere having a diameter ranging from about 10 nanometers

to about 50 nanometers." (See column 21, claim 13). With regard to the instantly claimed recitation of "nanocomposite produced by a process comprising …", such a limitation is a product by process limitation and is not given patentable weight. "Even though product-by-process claims are limited by the defined the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the product of the prior art, the claim is unpatentable even thought the prior product was made by a different process." (See *In re Thorpe*, 227 USPQ 964 (Fed. Cr. 1985)). For the foregoing reasons the instant invention is anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-6, 8-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talton (International Application Published under the PCT WO 00/74657 A1, Published 12/14/2000) in view of McGill et al. (US Patent 6025036, Published 02/15/2000).

Applicant Claims

Applicant claims a drug nanoparticle obtained by irradiating laser beam to a target composed of drug powder and protein, the method of manufacturing such a medical agent, and an apparatus for manufacturing such a medical agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Talton teaches, “Methods for coating particles and particles produced thereby” (See title). “Such particulates (cores) include, but are not limited to, drugs, pharmaceuticals for human or animal use, cosmetics, pesticides, herbicides, fungicides, paints and pigments, as well as inert particles for which a thin coating is desirable. Of course, this invention is also applicable to the application of thin layers of active materials to inert particles. Examples might include nanoparticles having biologically active coatings, such as antigens, nucleic acids, proteins, or even pharmaceuticals. The possibilities and combinations are numerous.” (See page 10, Lines 16-20 and page 11, Lines 1-2). "In this invention, PLD or pulsed laser ablation is used in the preparation of ultrafine, fine and granular drugs particles/particulate materials having atomic or nanometric thick coatings that impart improved pharmaceutical properties." (See page 12, Lines 17-19). “The method of the present invention generally involves physical vapor deposition (PVD) of polymer coating onto the surface of the target particulate.

techniques for achieving PVD are well-known in the art and include … laser ablation of a target material to produce a flux of coating particulate materials, which are then contacted with core particulate material, and allowed to form a coating thereon. A most preferred method is laser ablation." (See page 12, Lines 2-7). "Through regulation of the physical parameters of the deposition process (including background gas and pressure and coating exposure time) the skilled artisan may now for the first time prepare a variety of particulate drugs that comprise ultrafine particulate coatings." (See page 13, Lines 5-7). "Operating the coating process at approximate atmospheric pressure allows for continuous production process."(See page 14, Lines 4-5). "In addition, mechanical agitation may be included from the bottom to improve the fluidization at lower gas flow rates. A relatively inert atmosphere is maintained by constantly flowing a gas such as helium into the chamber." (See page 14, Lines 14-16). "The invention is operated such that the coating chamber has a pressure of around atmospheric pressure, which may be a pressure as low as about 10 Torr to as high as about 2500, or any pressure in between." (See page 14, Lines 20-22). "The methods of the present invention may even be used to coat nucleic acids to inert particles ..." (See page 17, Lines 2-3). "The materials employed in the coating process are preferably materials such that when ablated by an energy source, comprise a vapor of discrete particles that are extremely small – typically preferred are coating particles that are sized on the order of from about 1 to about 1000 nanometers in average diameter." (See page 15, Lines 6-9). "In certain applications, it may also be desirable to coat the drug particles with mixtures of two or more coating materials. Such coating materials may be prepared so that each member

of the plurality of coating materials may be simultaneously ablated and applied to the to the surfaces of the drug particles …" (See page 27, Lines 1-4). Talton further teaches an "apparatus for coating particulates". (See page 19, Line 10). "A nanometer-thin layer of target material absorbs the energy from the laser pulse and the surface is rapidly heated and expands from the target in the form of a plume of ablated atomic to micrometer sized particles. The plume of particles is then deposited onto the fluidized core particles." (See page 19, Lines 16-19). "The core particles, or particulate materials, are preferably fluidized within the coating chamber to improve the uniformity of coating." (See page 20, Lines 20-21). "Fluidization may also be achieved by mechanical mixing ..." (See page 21, Line 3). "A mechanical vibrator … can be used in conjunction with the fluidization to prevent particle agglomeration and apply fluidization at lower gas flow regimes." (See page 22, Lines 12-14 and Figure 1).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Talton lacks a teaching wherein the irradiation of the target is preformed under a pressure of 1 to 1000 Pa.

McGill et al. teach that pulse laser deposition in a particularly preferred embodiment is carried out at 0.1Torr (13.3Pa) to 1 Torr (133.3 Pa). "Generally, the lower the pressure the faster the deposition." (See column 8, Lines 30-43).

Furthermore, Talton teaches a target material comprising nucleic acid which is subjected to irradiation by a laser beam thereby creating nanoparticles which are deposited on an inert carrier. The instant claims (2, 4, 6, and 12) are directed to a target

material comprising a drug powder as well as a protein material. Talton teaches that the target material can be a combination of materials including organic materials such as pharmaceuticals as well as proteins. Although Talton does not instantly envisage the instant claims, Talton does make such a target material obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Talton with McGill et al. One would have been motivated to do so because McGill et al. teach that reduce pressure results in a faster more efficient means of deposition when pulse laser deposition is used.

It would have been obvious to one of ordinary skill in the art to use a combined coating composition of both nucleic acid and protein. One would have been motivated to do so because Talton teaches that combined composition is possible and thereby giving added applicability to particulate. For the foregoing reasons the instant invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
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